



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,137	06/28/2000	Michael E. Moseley	500.003US1	5608

7590 11/02/2005

Mark A Litman
Mark A Litman & Associates PA
York Business Center Ste 205
3209 W 76th Street
Edina, MN 55402

EXAMINER

JUNG, WILLIAM C

ART UNIT	PAPER NUMBER
----------	--------------

3737

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/606,137	Applicant(s) MOSELEY ET AL.	
	Examiner William Jung	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-7,9,11-26,29 and 54-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-7,9,11-26,29 and 54-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed July 29, 2005 have been fully considered but they are not persuasive.

After further consideration of the applicant's amendment and response, examiner respectfully disagrees. In regards to amended independent claims 5, 6, 7, 17, 23, and 29 and new claim 64, the added limitation sensing a nonviability of transplanted progenitor or stem do not distinguish over Lemelson in view of Palti. More specifically, in Lemelson's method and system is directed to imaging and quantifying the target area where the viability of the implanted cells are detected by the specific groups of biochemical release from the cells that are healthy, sick or diseased, and genetically defected. The quantification via imaging of the cells indicates viability or nonviability of the implanted cells. Therefore, the previous rejection is maintained and repeated below.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 5-7, 9, 11-19, 23, 25, 26, 29, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Lemelson* (US 5,865,744) in view of *Palti* (US 5,190,041).

Lemelson substantially discloses all claimed features in claims 5-7, 13-18, 23, 25, 26, 29, and 64. Lemelson discloses a method in which tissue injected with therapeutic agents for

Art Unit: 3737

effecting tissue engineering that is selective to growth of various cell types within a target tissue of a patient such as growth factor or cytokine (e.g. EGF, PDGF, fibroblast growth factors, etc.) and monitoring the viability of the tissue condition in response to the growth factor agent above via imaging method such as x-ray, computed tomography, magnetic resonance imaging, positron emission tomography, or ultrasound. The method includes imaging of the region of interest where the growth factor is to be transplanted (col. 1, line 16 – col. 2, line 16; col. 3, line 28 – col. 4, line 45; 10, lines 22-55). Although, Lemelson does not explicitly state that the transplanted agent is progenitor or stem cells, Lemelson's use of growth factor materials and cells as transplant agent to proliferate cell or tissue growth is equivalent to the intended purpose of the claimed invention in current application. In addition, Lemelson's disclosure is directed to locating the viable site and imaging the cells involved with the transplant. However, Lemelson does not disclose indicating viability by determining from a group consisting of cell activity, cell inactivity, cell growth, cell death, specific cell function and dysfunction, volumetric expansion of cell population and volumetric decrease of cell population. However, the monitoring of transplanted cells after injection is well known in the art as evident by Palti's teaching where Palti discloses that the implanted cells are detectable by imaging method to determine concentration over a period of time, which in turn determines the growth characteristics, increasing or decreasing which is due to cell death or proliferation (col. 2, line 63- col. 4, line 43; col. 4, line 65 – col. 5, line 13). Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings of Lemelson with cell growth monitoring method as taught by Palti to achieve the claimed invention.

Claims 9, 11, 12, and 19: In addition, Palti discloses that the concentration of cell growth measurement can be determined via glucose concentration effected by the cell growth (col. 6, lines 29-56).

Claims 54-63: Lemelson discloses that the above procedure includes system of digitizing images of the target area where the transplant or injection of progenitor cells are made and monitoring the viability (col. 14, lines 1-11).

4. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Lemelson* and *Palti* as applied to claims 17-19 above, and further in view of *Johnson et al* (US 6,051,208).

Lemelson and Palti substantially disclose all claimed features in claims 20-23 as described above. However, neither Lemelson nor Palti discloses the method above to include hyperpolarized gas with MRI device to detect the cell growth. It is well known in the art as taught by Johnson et al that MRI method can be improved by using hyperpolarized gas such as Xenon can be used to enhance the image quality (col. 1, lines 25-52; col. 2, line 8 – col. 3, line 15). Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings of Lemelson and Palti's method with Johnson et al's MRI contrast imaging to improve the quality of the results.

5. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Lemelson* and *Palti* as applied to claim 5 above, and further in view of *Dinsmore* (US 6,140,116).

Lemelson and Palti substantially disclose all claimed features in claim 24 as described above. However, neither Lemelson nor Palti discloses the method above to detect at least one of choline, NAA, GABA, phosphocholine, and creatine, i.e. neurotransmitter. This method however is well known in the art as demonstrated by Dinsmore where a method of detecting at

Art Unit: 3737

least one of choline, NAA, GABA, phosphocholine, and creatine, i.e. neurotransmitter (col. 3, line 44 – col. 4, line 9; col. 16, lines 40-56). . Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings of Lemelson and Palti with cell growth monitoring using choline, NAA, GABA, phosphocholine, and creatine, i.e. neurotransmitter as taught by Dinsmore to achieve the claimed invention.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung, Ph.D. whose telephone number is 571-272-4739. The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3737

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

WJ

October 30, 2005



ALI IMAM
PRIMARY EXAMINER